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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,364	12/14/2006	Larry I. Benowitz	701039-054385	1709

7590 06/11/2009

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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
06/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,364	BENOWITZ ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicants are required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10 (each in part), 15, 17 (in part), 31-38 (each in part), 43 and 45 (in part), drawn to a method for stimulating the axonal growth of central nervous system (CNS) neurons said method comprising the steps of: a. contacting CNS neurons with an effective amount of an NgR antagonist; and b. contacting CNS neurons with an effective amount of an agent that activates the growth pathway of CNS neurons, **wherein the NgR antagonist is an antibody that binds NgR**.

Group II, claim(s) 1-10 (each in part), 17 (in part), 18-21, 31-38 (each in part), 45 (in part) and 46-49, drawn to a method for stimulating the axonal growth of central nervous system (CNS) neurons said method comprising the steps of: a. contacting CNS neurons with an effective amount of an NgR antagonist; and b. contacting CNS neurons with an effective amount of an agent that activates the growth pathway of CNS neurons, **wherein the NgR antagonist is a peptide (other than an antibody) that binds NgR**.

Group III, claim(s) 1-9 (each in part), 11, 31-37 (each in part) and 39, drawn to a method for stimulating the axonal growth of central nervous system (CNS) neurons said method comprising the steps of: a. contacting CNS neurons with an effective amount of an NgR antagonist; and b. contacting CNS neurons with an effective amount of an agent that activates the growth pathway of CNS neurons, **wherein the NgR antagonist is an agent that inhibits the expression of NgR**.

Group IV, claim(s) 1-9 (each in part), 12-14, 31-37 (each in part) and 40-42, drawn to a method for stimulating the axonal growth of central nervous system (CNS) neurons said method comprising the steps of: a. contacting CNS neurons with an effective amount of an NgR antagonist; and b. contacting CNS neurons with an effective amount of an agent that activates the growth pathway of CNS neurons, **wherein the NgR antagonist is an agent that inhibits the activity of a downstream signaling molecule that is activated by NgR**.

Group V, claim(s) 1-9 (each in part), 16 and 17 (in part), 31-37 (each in part), 44 and 45 (in part), drawn to a method for stimulating the axonal growth of central nervous system (CNS) neurons said method comprising the steps of: a. contacting CNS neurons with an effective amount of an NgR antagonist; and b. contacting CNS neurons with an effective amount of an agent that activates the growth pathway of CNS neurons, **wherein the NgR antagonist is an antibody that binds to a NgR ligand**.

Group VI, claim(s) 1-9 (each in part), 17 (in part) and 22-24, 31-37 (each in part), 45 (in part) and 50-52, drawn to a method for stimulating the axonal growth of central nervous system (CNS) neurons said method comprising the steps of: a. contacting CNS neurons with an effective amount of an NgR antagonist; and b. contacting CNS neurons with an effective amount of an agent that activates the growth pathway of CNS neurons, **wherein the NgR antagonist is a soluble NgR protein**.

Group VII, claim(s) 1-9 (each in part), 25, 31-37 (each in part) and 53, drawn to a method for stimulating the axonal growth of central nervous system (CNS) neurons said method comprising the steps of: a. contacting CNS neurons with an effective amount of an NgR antagonist; and b. contacting CNS neurons with an effective amount of an agent that activates the growth pathway of CNS neurons, **wherein the NgR antagonist is a nucleic acid aptamer that binds to NgR**.

Group VIII, claim(s) 1-9 (each in part), 26, 27, 29-37(each in part) 54, 55, 57 (in part) and 58 (in part), drawn to a method for stimulating the axonal growth of central nervous system (CNS) neurons said method comprising the steps of: a. contacting CNS neurons with an effective amount of an NgR antagonist; and b. contacting CNS neurons with an effective amount of an agent that activates the growth pathway of CNS neurons, **wherein the NgR antagonist is a defective NgR encoded by DNA**.
Group IX, claim(s) 1-9 (each in part), 28, 29-37 (each in part), 56, 57 (in part) and 58 (in part), drawn to a method for stimulating the axonal growth of central nervous system (CNS) neurons said method comprising the steps of: a. contacting CNS neurons with an effective amount of an NgR antagonist; and b. contacting CNS neurons with an effective amount of an agent that activates the growth pathway of CNS neurons, **wherein the NgR antagonist is a clostridium botulinum C3 ADP-ribosyltransferase encoded by DNA**.

Group X, claim(s) 59, 60 and 63, drawn to a pharmaceutical composition comprising a NgR antagonist and an agent that activates the growth pathway of CNS neurons, **wherein the NgR antagonist is an antibody.**

Group XI, claim(s) 59-61 and 63, drawn to a pharmaceutical composition comprising a NgR antagonist and an agent that activates the growth pathway of CNS neurons, **wherein the NgR antagonist is a peptide that binds to NgR.**

Group XII, claim(s) 59, 60, 62 and 63, drawn to a pharmaceutical composition comprising a NgR antagonist and an agent that activates the growth pathway of CNS neurons, **wherein the NgR antagonist is a soluble NgR protein.**
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The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XII is that they all relate to a method for stimulating the axonal growth of central nervous system (CNS) neurons comprising the steps of: a. contacting CNS neurons with an effective amount of an NgR antagonist; and b. contacting CNS neurons with an effective amount of an agent that activates the growth pathway of CNS neurons. However, US-2003/0124704 to Strittmatter et al. teaches methods and compositions for stimulating the axonal growth of central nervous system (CNS) neurons (e.g. in a method of treating a CNS disorder) comprising administration of therapeutically effective amounts of an NgR antagonist and a growth factor (see paragraphs 0001, 0017, 0018, 00195 and 00196). Thus, the technical feature linking the inventions of Groups I-X does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Requirement for Election of Species Within Groups I-XII

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Agents that activate the growth pathway of CNS neurons:

a. Inosine

b. Oncomodulin

c. TGF-β

d. NGF

e. BDNF

f. NT-3

g. CTNF

h. IL-6

i. GDNF

j. D-mannose

k. Gulose

l. Glucose-6-phosphate

Applicants are required, in reply to this action, **to elect a single species** to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also **identify the claims readable on the elected species, including any claims subsequently added**. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species are structurally and functionally distinct molecules, wherein a search of one species does not encompass a search of any other species.

Requirement for Election of Species Within Groups II and XI

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Peptide sequences:

m. SEQ ID NO: 1

n. SEQ ID NO: 2

o. SEQ ID NO: 3

p. SEQ ID NO: 4

q. SEQ ID NO: 5

r. SEQ ID NO: 6

s. SEQ ID NO: 7

t. SEQ ID NO: 14

u. SEQ ID NO: 15

v. SEQ ID NO: 16

Applicants are required, in reply to this action, **to elect a single species** to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also **identify the claims readable on the elected species, including any claims subsequently added**. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species are structurally and functionally distinct amino acid molecules, wherein a search of one species does not encompass a search of any other species.

Requirement for Election of Species Within Groups VI and XII

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Peptide sequences:

w. SEQ ID NO: 8

x. SEQ ID NO: 9

y. SEQ ID NO: 10

z. SEQ ID NO: 11

aa. SEQ ID NO: 12

bb. SEQ ID NO: 13

Applicants are required, in reply to this action, **to elect a single species** to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also **identify the claims readable on the elected species, including any claims subsequently added**. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species are structurally and functionally distinct amino acid molecules, wherein a search of one species does not encompass a search of any other species.

Note: For the above election of species requirements, applicant is invited to provide sequence alignments for all of the sequence identifiers recited by the claims that show how these sequences are related. If, for example, the different identifiers have residues in common, and a search of one identifier can be used to search multiple identifiers, applicant may be entitled to examination of more than one species from each requirement outlined above.

Applicants are advised that the reply to this requirement to be complete must include (i) **elections of species and invention** to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) **identification of the claims encompassing the elected invention**.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicants traverse on the ground that the inventions or species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached at (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G.E./

Gregory S. Emch
Patent Examiner
Art Unit 1649
09 June 2009

/Daniel E. Kolker/
Primary Examiner, Art Unit 1649
June 9, 2009